3006-1.KAG/393348

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: patent application of:		
	Dusan Pavcnik	
	Josef Rösch	
	Frederick Keller	
		Group Art Unit:
Serial No.:	09/849,044	3738
Filed:	May 4, 2001	
For:	ENDOVASCULAR STENT GRAFT	Examiner: Alvin J. Stewart

DECLARATION OF DR. MICHAEL C. HILES
UNDER 37 C.F.R. §1.132 TRAVERSING REJECTION

Commissioner of Patents and Trademarks
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Michael Hiles, hereby aver as follows.

1. I hold a Bachelor of Science degree in Electrical Engineering from Purdue University (1987), a Master of Science degree in Electrical Engineering with a specialization in Biomedical Engineering from Purdue University (1989), and a Ph.D. degree in Veterinary Physiology and Pharmacology from Purdue University (1992) directed toward remodeling vascular graft materials.

2. I have considerable research and work experience in fields related to remodelable tissue graft materials. After receiving my Ph.D., from 1992 to 1995 I was employed by the Hillenbrand Biomedical Engineering Center in the position of Associate Research Scholar focusing specifically on the biomechanics and implant response characteristic of remodelable

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tissue graft materials in the form of blood vessels, hernia repair devices and orthopedic implants. From 1995 to the present, I have been employed by Cook Biotech Incorporated, West Lafayette, Indiana, starting in the position of Research Manager, and currently holding the position of Vice President for Research and Clinical Affairs. My work has focused upon remodelable tissue graft implants in the areas of manufacturing, product development, and studies of the biological, mechanical, physical and chemical characteristics of such graft implants. Cook Biotech Incorporated is a sister company to Cook Incorporated, assignee of the present application, these companies both being subsidiaries of Cook Group Incorporated.

3. I have reviewed and am familiar with the above-identified patent application, including claims 1 and 3-9 presently pending. I am aware that these claims require the use of "a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue" in certain stent graft configurations. In particular I am aware that claim 1 requires:

> a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue, secured to the at least one stent and extending therealong between the proximal and distal ends, wherein the covering is a sleeve that initially has a length about equal to twice the length of the at least one stent, a first portion of the sleeve extends along and complements inside surface of the at least one stent, and a second portion of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof, and wherein the first portion and the second portion of the sleeve are secured to at least the distal end of the at least one stent.

And, I am aware that claim 3 requires:

> a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue, secured to the at least one stent and extending therealong between the proximal and distal ends, wherein the covering is a sleeve that initially has a length about equal to twice the length of the at least one stent, a first portion of the sleeve extends along and complements inside surface of the at least one stent, and a second portion of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof, wherein the stent graft further comprising a plurality of stents connected together to form a stent frame with lumens of the respective stents coaligned to form a common continuous

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lumen extending from a distal stent frame end to a proximal stent frame end, and the covering extending therealong between the proximal and distal stent frame ends.

4. Remodelable materials as recited in claims 1 and 3 are understood in the art to possess properties that balance degradation of the implanted material with new native tissue ingrowth to replace the implanted material as it is degraded. The use of such remodelable materials in stent grafts with the claimed covering features presents significant advantages in device manufacture and use. When the ends of the claimed covering material are attached at the stent's distal end as in independent claim 1, the sutures or other attachment means responsible for securing the loose sleeve ends will not need to be placed somewhere along the middle of the stent(s). This means that any attachments along the central portion of the device can be eliminated or minimized. This can be beneficial because any foreign materials (such as sutures) that interrupt the remodelable material field covering the stent(s) can initiate a foreign body response upon implantation in a patient. This foreign body response could have an adverse impact upon the balanced graft resorption and tissue ingrowth in the remodeling process. Further, where multiple connected stents are used in the stent graft structure as in independent claim 3, the sleeve covering extending over all of the connected stents provides the ability to encompass and cover the connected portions of the multiple stents, including any materials such as filaments or other structures used in the connection. Such filaments or other structures can also present foreign bodies that could initiate a response that interferes with the desired, balanced remodeling function of the covering as it contacts bodily lumen surfaces.

5. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dated: 03 Apr 06

Michael C. Hiles, Ph.D.

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